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| 10/682,220 | 10/09/2003 | Sonar Shah | P0010137.02 | 8096 |

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| EXAMINER | |
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| SONNETT, KATHLEEN C | |

| ART UNIT | PAPER NUMBER |
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| 3731 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| | | |
|---|---|---|
| **Office Action Summary** | **Application No.**<br>10/682,220 | **Applicant(s)**<br>SHAH ET AL. |
| | **Examiner**<br>KATHLEEN SONNETT | **Art Unit**<br>3731 |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 April 2009*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10,13-29,31-37 and 70-99* is/are pending in the application.
  4a) Of the above claim(s) *90-99* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-10,13-29,31-37 and 70-89* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☐ All b)☐ Some * c)☐ None of:
    1.☐ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/7/2009 has been entered.

### Correction of Inventorship

2. In view of papers filed on 4/20/2009, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding Stanten C. Spear.

3. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of office records to reflect the inventorship as corrected.

### Election/Restriction

4. A restriction requirement was sent out 1/16/2007 between Group I (single sheath: claims 1-69), Group II (sheath assembly: claims 70-89), and Group III (method of positioning sheath: claims 90-99) and applicant elected Group I, claims 1-69, in a response filed 2/16/2007. The restriction between Groups I and II was based on Group I being drawn to a single sheath and Group II being drawn to a two sheath system. However, the claims of Group I were amended to include a second sheath and the Applicant received actions on the merits for the amended claims. Therefore, the restriction requirement between Groups I and II has been withdrawn and

claims 70-89 are no longer considered withdrawn and have been acted on in this action. However, the restriction requirement between the apparatus and method (claims 90-99) claims still stands and therefore claims 90-99 remain withdraw.

### *Specification*

5. The disclosure is objected to because of the following informalities: the “Related Applications Section” (par. 1) should be updated to reflect that App. 10/016,114 is now issued US Patent 7,065,394.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. **Claim 70-73 and 75-78** are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 6,066,126; “Li”) in view of Bosley, Jr. et al. (US 5,081,997; “Bosley”). Li discloses a guide catheter comprising an elongated inner sheath (4) that is slidably received within an outer sheath (6) and is capable of being positioned so that the distal tip protrudes from a distal end of the outer sheath. Li fails to disclose that the tip is fully radiopaque and has a length greater than or equal to approximately 0.2 inch.

8. Bosley teaches mixing particles with a base material during the formation of an elongated, flexible tube such that the entire tube is radiopaque and echogenic (see entire document). This is advantageous for imaging purposes. Therefore, it would have been obvious

to one of ordinary skill in the art to modify the device of Li to construct the elongated sheath (4) such that it is both echogenic and radiopaque as made obvious by Bosley for enhanced imaging properties. Regarding the length of the tip, since the entire sheath is radiopaque and echogenic, the tip can be considered the last .08 inches or the last 0.2 inches, or the last 0.4 inches. That is, the tip must only be a section of the tube that starts at some point along the length of the tube and extends to the distal most point of the tube. Bosley teaches using tungsten particles (see claim 36) and it would have been obvious to use a salt form, such as tungsten carbide since it is well known to use radiopaque particles in their salt form.

9. Regarding claims 73, 75, and 76, Li discloses a first resilient preformed curve included in the tip. The first curve (32) sweeps out an angle of approximately 40 to 90 degrees (col. 3, ll. 28-30). This angle is included in the tip portion, which has a length greater than or equal to 0.08 inches (2.032cm). Segment 34 alone can have a length of 2 cm (col. 3, ll. 19-20).

10. Regarding claims 77 and 78, the tip also includes a second resilient preformed curve (28) extending from the first resilient curve. This curve sweeps out an angle of about 90 degrees (col. 3 ll. 25-27). Since both the first and second curve sweep out angles of 90 degrees, together, they sweep out an angle greater than approximately 90 degrees.

11. **Claims 1-10, 13, 36, and 70-73** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho (US 5,109,830) in view of Stoy et al. (US 5,368,048) and Hibbs et al. (US 4,950,257; “Hibbs”). Cho discloses a guide catheter capable of affording coronary vasculature branch sub-election comprising a first elongated sheath having a proximal end, distal tip and inner channel including a radiopaque distal tip and a second elongated sheath adapted to pass through the inner channel of the first elongated sheath to cannulate primary and secondary veins and having a proximal end, distal tip and inner channel. The tip of the inner sheath is also radiopaque. Cho fails to disclose the following: regarding claim 70, that the tip is

greater than or equal to .02 inch in length and is fully radiopaque, and regarding claim 1, that the tip of each sheath is both radiopaque and echogenic, a braid reinforces the wall of the first sheath, the tip of the first sheath is made of tungsten carbide particles (70 to 75 % by weight having an average diameter of less than 500 nanometers), and the tip of the second sheath has a hardness of between 25D and 35D durometer with a length greater than or equal to 0.08 inch.

12. Regarding the reinforcing braid within the sheath, such a feature is not considered a patentable distinction since it is old and well known in the art to use reinforcing braids in sheaths to improve pushability of the device through vasculature. This well-known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion of official notice in the previous office action (see MPEP 2144.03 "C", final paragraph). Stoy teaches an alternative manner of forming a radiopaque tip on an elongated medical device which includes mixing radiopaque particles into a plastic composition that forms the tip (abstract). In particular, Stoy teaches using tungsten particles in the range of about 0.1 microns to about 50 microns (100nm to 50,000nm) in order to impart this radiopacity to the plastic material (col. 5, ll. 54-64). It would have been obvious to incorporate tungsten particles into the polymer material forming the sheath tips of Cho since such a modification can be considered a substitution of one known method of imparting radiopacity to the tip of an elongated medical device for another with predictable results. Regarding the use of tungsten in the form of tungsten carbide, it is well known to use radiopaque particles in salt form. Stoy further teaches that it is known to use between 50 to 85 percent by weight to impart adequate radiopacity and therefore one skilled in the art would have found the claimed range of 70 to 75 percent by weight of tungsten obvious (col. 6, ll. 20-26). Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ 233). Regarding the

echogenicity of the tip, although not expressly disclosed, it appears that the tips of the sheaths of Cho in view of Stoy are inherently echogenic since, according to the instant application, a tip with the claimed size and weight of tungsten carbide particles is echogenic. Hibbs teaches that appropriate shore hardness for a soft, atraumatic tip on a sheath can be about 30D (col. 4 ll. 40-41) and further discloses a length for the tip of about 0.5 inch. It would have been obvious to impart such a hardness to the tip of Cho so that it is appropriately atraumatic, thereby minimizing the potential for tissue damage.

13. Regarding claim 70, as discussed above, Stoy makes obvious making a tip radiopaque by incorporating radiopaque materials in to the polymer forming the tip and therefore makes obvious a fully radiopaque tip and Hibbs teaches sizing a tip portion with a length greater than 0.2 inch.

14. Regarding claims 4 and 5, Hibbs teaches a length of 0.5 inches, which reads on the claimed ranges of claims 1, 4, and 5. However, the claimed range of claim 3 is being considered obvious since it is well known to adjust tip length depending on the intended use of the device and is being considered a matter of design choice to one of ordinary skill in the art which fails to patentably distinguish the claimed invention from the prior art of Cho as modified by Hibbs. It is noted that applicant has not disclosed any particular advantage gained, purpose served, or problem solved by using a tip between 0.08 - 0.2 inches as opposed to the other claimed ranges. Furthermore, it has been held that, where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller,* 105 USPQ 233).

15. Regarding claims 6-8, Stoy teaches nanometer sized particles of 100 nanometers (col. 5 ll. 60-63) and it would have been obvious to use this sized particle in both sheaths.

16. Regarding claims 9 and 10, Stoy teaches using 50 to 85% by weight of tungsten particles to impart radiopacity to a sheath and therefore makes obvious the claimed values of percentage by weight of tungsten carbide particles.

17. Regarding claim 36, the distal tip of the second elongated sheath is atraumatic since it is soft.

18. Regarding claims 13 and 73, the tip includes a preformed curve (col. 1, ll. 38-40 of Cho).

19. **Claims 14, 23, 24, 31-35, 37, 74 , 83, and 84** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Stoy and Hibbs as applied to claim 1 above, and further in view of Wijayarathna et al. (US 4,563,181) ("Wijayarathna"). Modified Cho discloses the invention substantially as stated above but fails to disclose that the distal tip of the second elongated sheath includes a resilient preformed curve of greater than about 180 degrees and a tapered tip portion or that the second elongated sheath's tip is coupled to the remainder of the sheath by a butt joint.

20. Wijayarathna teaches a tapered tip portion (see distal end in fig. 1 and 2) which facilitates insertion and advancement of the instrument through vasculature. Wijayarathna also teaches that an atraumatic soft tip can be attached to a catheter using a heat fused butt joint (col. 3 ll. 44-45; abstract). Such a joint allows a continuous tube to be formed. The stiffness of the proximal segment is higher than the stiffness of the tip. It would have been obvious to one skilled in the art to have modified Cho in view of Wijayarathna to include a tapered tip portion as well as a butt fused joint between the tip and remainder of the second elongated sheath in order to ensure a strong connection between the tip and proximal portion of the second elongated sheath.

21. Regarding claim 37, the second elongated sheath includes a proximal segment and a distal tip coupled together as taught by Wijayarathna. Since the tip is tapered, it has an outer diameter less than that of the proximal segment of the sheath.

22. Regarding claims 33 and 34, the distal tip is heat fused and includes a tapered transition. Regarding the use of RF energy or an RF die, such limitations can be considered product-by-process. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious form a product of the prior art, the claims are unpatentable even though the prior product was made by a different process (*In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964,966 (Fed. Cir. 1985)).

23. **Claims 15-18 and 75-78** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Stoy and Hibbs as applied to claim 1 above, and further in view of Li et al. (US 6,066,126). Modified Cho discloses the invention substantially as stated above but fails to disclose resilient preformed curve in the second elongated sheath.

24. Regarding claims 15, 16, 75, and 76, Li teaches including a first resilient preformed curve included in the tip. The first curve (32) sweeps out an angle of approximately 40 to 90 degrees. These angles are both included in the tip portion, which has a length greater than or equal to 0.08 inches (2.032cm). Segment 34 alone can have a length of 2 cm (col. 3, ll. 19-20).

25. Regarding claims 17, 18, 77, and 78, the tip also includes a second resilient preformed curve (28) extending from the first resilient curve. This curve sweeps out an angle of up to about 90 degrees. Since both the first and second curve sweep out angles of 90 degrees, together, they sweep out an angle greater than approximately 90 degrees.

26. It would have been obvious to one skilled in the art to have modified Cho to include such preformed curves in the second elongated sheath as taught by Li in order to be able to better direct the catheter into cardiac tissue so that the device can be used to introduce an electrophysiology catheter to the atrium (col. 1, ll. 5-11; col. 2 ll. 24-39).

27. **Claims 17, 19, 20, 77, 79, and 80** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Stoy and Hibbs as applied to claims 13 and 73 above, and further in view of Rickerd (US 5,322,509). Modified Cho discloses the invention substantially as stated above but fails to disclose resilient preformed curve in the second elongated sheath.

28. Rickerd teaches including first and second resilient curves in the tip of a sheath that form an amplatz shape (fig. 1). Such a configuration is useful because it allows the sheath to be utilized to enter either left or right ostia without catheter exchange by rotation of the catheter around its axis (see abstract) and therefore it would have been obvious to one skilled in the art to have modified Cho to include such preformed curves in the second elongated sheath as taught by Rickerd.

29. Regarding the angles claimed in claim 19 and 79, at the time of the invention, it would have been an obvious matter of design choice to one skilled in the art to employ angles of between 160 and 180 for the first curve and angles between 40 and 80 for the second curve. Rickerd does not disclose the degrees of the angles swept out by each curve (C and D). However, as seen in fig. 1, the first curve "C" appears to be at least twice the size of and in the opposite direction of second curve "D". Since applicant has not disclosed any criticality regarding the degree ranges such as a particular problem solved, advantage achieved, or a particular usage that is dependent on these angles, and the figures of Rickerd suggest angles that are around (120-160) and (40-60) degrees, it appears that the device of Rickerd would perform the function of snaking through coronary arteries equally well with the curves of Rickerd

or the claimed curves. Therefore, it would have been prima facie obvious to modify Cho in view of Rickerd to obtain the invention as specified in claims 19 and 79 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Cho as modified by Rickerd.

30. **Claims 17, 20-24, 26, 28, 77, 80-84, 86, and 88** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Stoy and Hibbs as applied to claims 13 and 73 above, and further in view of Tanaka et al. (US 6,039,723; "Tanaka"). Modified Cho discloses the invention substantially as stated above but fails to disclose a resilient preformed curve in the second elongated sheath.

31. Tanaka teaches that it is old and well known to include preformed curves on a sheath type instrument in order to facilitate advancement of the device within tissue (fig. 1) in the desired direction. Tanaka discloses first, second, and third preformed curves (see fig. 1). When taken together, the angles that each one sweeps out will be greater than 100 degrees since the first curve by itself sweeps out an angle of around 180 degrees. The two most distal curves form an amplatz shape. The distal tip also includes a tapered transition (see "232" in fig. 12 and 13). It would have been obvious to one skilled in the art to have modified Cho to include such preformed curves in the second elongated sheath as taught by Tanaka in order to be able to better direct the catheter into cardiac tissue.

32. **Claims 17, 24-27, 77, and 84-87** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Stoy and Hibbs, as applied to claims 13 and 73 above, and further in view of Lentz (US 6,022,341). Modified Cho discloses the invention substantially as stated above but fails to disclose resilient preformed curve in the second elongated sheath.

33. Lentz teaches including preformed curves on a sheath type instrument in order to facilitate advancement of the device within tissue in the desired direction (fig. 3). Lentz discloses

first and second preformed curves and a tapered portion (30) that is proximal to both curves (fig. 3). It would have been obvious to one skilled in the art to have modified Cho to include such preformed curves in the second elongated sheath as taught by Lentz in order to be able to better direct the catheter into cardiac tissue.

34. **Claims 21, 28, 29, 81, 88, and 89** rejected under 35 U.S.C. 103(a) as being unpatentable over Cho in view of Stoy, Hibbs, and Lentz as applied to claims 17 and 77 above and further in view of Tanaka et al (US 6,039,723; "Tanaka"). Modified Cho discloses the invention substantially as stated above but fails to disclose a third preformed curve distal of the tapered transition.

35. However, Tanaka discloses that it is old and well known to include three resilient preformed curves in a distal tip. It would have been obvious to one skilled in the art to have further modified Cho to include a third curve as taught by Tanaka in order to facilitate advancement of the device within the heart. Since Lentz teaches including such preformed curves distal of a tapered transition, it would have been obvious to one skilled in the art to have provided the third curve as taught by Tanaka distal of the tapered transition.

### ***Response to Arguments***

36. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Graf et al. (US 2001/0037065) discloses a radiopaque tip formed from plastic mixed with 70 to 75% by weight tungsten particles that are sized at 500 nanometers (see abstract and par. 15).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 2/4/2010

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2/10/10